REMARKS

I. Support for Amendments

The specification was amended in order to correct the sequence identification information and acknowledge the use of trademarks, as suggested by the Examiner. The drawings were amended in order to add the appropriate sequence identification numbers, as suggested by the Examiner. The claims were amended to more clearly define the invention. Support for newly added claims 69-78 can be found throughout the Specification, for example, on page 5, line 33, page 6, lines 6-22, page 7, line 10 to page 8, line 16, page 9, lines 4-10, pages 10-11, page 14, line 12 to page 15, line 3, page 17, lines 20-29, page 18, lines 5-13, pages 23-24, Table 1, and Figures 1-3. Accordingly, no new matter is added by this Amendment and entry thereof is respectfully requested.

II. Objection to the Drawings

The Examiner objected to the drawings because they did not properly identify the sequences included in the drawings as specified in 37 CFR §1.821 through 1.825. Applicants submit herewith amended drawings that identify the appropriate sequence identification numbers. Approval of the amended drawings is respectfully requested.

III. Objection to the Information Disclosure Statement

The Examiner objected to the information disclosure statement by asserting that a listing of references in the specification is not a proper information disclosure statement. In view of the

Information Disclosure Statement filed by Applicants on March 27, 2003, withdrawal of this objection is respectfully requested.

IV. Specification

The Examiner has noted the use of trademarks in the application. The specification has been amended in order to respect the proprietary nature of the marks by capitalizing the trademarks and accompanying the marks by their generic terminology.

V. Rejection of claims 48-68 under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 48-68 under 35 U.S.C. § 112, first paragraph, as the claims allegedly contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In view of the cancellation of claims 48-68, withdrawal of the rejection is respectfully requested.

New claims 69-78 are sufficiently supported in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. New claims 69 and 70, directed to a polypeptide/glycopolypeptide comprising the amino acid sequence of SEQ ID NO: 2, are adequately described in the specification in such a way so that the skilled artisan can envision the detailed structure of the isolated protein/glycoprotein sequence, as stated by the Examiner on pages 5 and 6 of the Office

Action.[1] In addition, new claims 71-74 are adequately supported by the specification. For example, page 14, line 32 to page 15, line 3, lists all of the amino acid positions that may be replaced by conservatively substituted amino acids. Furthermore, pages 10-11 of the specification describes algorithms used to determine which amino acid substitutions may be made. For instance, the specification describes the hydropathic and hydrophilic indices that enable those skilled in the art to determine which amino acids can be substituted for one another. In addition, Table 1 on page 30 of the specification provides specific examples of amino acid substitutions that maintain the unique human-species specific glycosylation of the glycopolypeptide of the invention. Furthermore, claims 75-78 are adequately supported throughout the specification, for example, on pages 8-9 where the importance of human specific ooycyte glycosylation on the biological activity of the ZP3 peptide is discussed. In addition, page 18, lines 5-13 of the specification lists suitable ovarian cell lines for human ZP3 expression while Example 3 on page 20 describes the inventors' expression of rhZP3 from PA-1 cells. Furthermore, Examples 7 and 8 on pages 23-24 demonstrate the sperm-binding and acrosome reaction inducing activity of the claimed polypeptide.

In analyzing the adequacy of the written description, it is determined if the description clearly allows persons of ordinary skill in the art to recognize that the inventor invented what is claimed. *See In re Gosteli*, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989). Because the specification provides a detailed description of the polypeptide and glycopolypeptide of SEQ ID NO: 2 and conservative amino acid substitutions thereof, and teaches a properly glycosylated

[1] In the latest Office Action, the Examiner refers to SEQ ID NO: 1 as meeting the written description requirements of 35 USC § 112, first paragraph. However, since the specification and all of the claims have been amended to recite SEQ ID NO: 2 instead of SEQ ID NO: 1 (see Paper #21, filed 2/28/01), the Applicant believes that the Examiner was actually referring to SEQ ID NO: 2 in this latest Office Action.

recombinant human ZP3 protein expressed by a human ovarian cell line, claims 69-78 are adequately described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Withdrawal of the rejection is respectfully requested.

VI. Rejection of claims 48-56 and 60-68 under 35 U.S.C. § 102(b) and (e)

The Examiner has rejected claims 48-56 and 60-68 under 35 U.S.C. § 102(b) and (e) as being anticipated by Dean (U.S. Patent No. 5,641,487). Dean is relied on in the Action for teaching a polypeptide and functional derivatives thereof, which have human ZP3 activity or human ZP3 antigenicity. In view of the cancellation of claims 48-56 and 60-68, withdrawal of the rejection is respectfully requested. It will be appreciated that new claims 69 -78 are not anticipated by Dean.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). "Every element of the claimed invention must be literally present, arranged as in the claim" for an invention to be anticipated. *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Dean does not teach the polypeptide of SEQ ID NO: 2, the polypeptide of SEQ ID NO: 2 having the amino acid substitutions of claims 71-74, or the expression of hZP3 by a human ovarian cell line. Therefore, Dean does not teach every element of claim 69-78, and, therefore, does not anticipate newly added claims 69-78.

VII. Rejection of claims 48-56 and 60-68 under 35 U.S.C. § 102(b) and (e)

The Examiner has rejected claims 48-56 and 60-68 under 35 U.S.C. § 102(b) and (e) as being anticipated by Dean (U.S. Patent No. 5,672,488). Dean is relied on in the Action for teaching a polypeptide and functional derivatives thereof, which have human ZP3 activity or human ZP3 antigenicity. In view of the cancellation of claims 48-56 and 60-68, withdrawal of the rejection is respectfully requested. Newly added claims 69-78 are not anticipated by Dean for the reasons discussed above.

VIII. Rejection of claims 57-59 under 35 U.S.C. § 103(a)

Claims 57-59 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Dean (U.S. Patent No. 5,641,487) or Dean (U.S. Patent No. 5,672,488) in view of Chamberlin et al. (Proc.Natl.Acad.Sci. USA, Developmental Biology, Vol. 87, pp. 6014-6018, August 1990) and in further view of Stern et al. (U.S. Patent No. 5,869,053). In view of the cancellation of claims 57-59, withdrawal of the rejection is respectfully requested. New claims 69 -78 are not obvious over the Dean, Chamberlin, and Stern references.

To properly make a rejection under 35 U.S.C. § 103, the Examiner has the initial burden of establishing a *prima facie* case of obviousness. Meeting this burden requires the Examiner to show first, that the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process. Second, the Examiner must establish that the prior art would have revealed that in so making or carrying out the claimed process, those of ordinary skill in the art would have had a reasonable expectation of

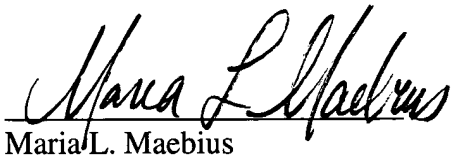
success. Both the suggestion and the reasonable expectation of success must be found in the prior art, not in Applicants' disclosure. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991), citing *In re Dow Chemical Co.,* 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Furthermore, it is well settled that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. *In re Geiger,* 2 U.S.P.Q.2d 1276 (Fed. Cir. 1987).

The deficiencies of the Dean patents were addressed above. Chamberlin and Stern do not remedy the deficiencies as they do not describe the claimed polypeptides. Accordingly, Applicants assert that none of the references, whether alone or in combination, teach or suggest the presently claimed invention of newly added claims 69-78. Applicants respectfully request that the rejection be withdrawn.

IX. CONCLUSION

In view of the foregoing remarks, Applicants believe that the application is in condition for allowance. However, if the Examiner disagrees, she is encouraged to call the undersigned at the number listed below in order to expedite the prosecution of this application.

Respectfully submitted,



Maria L. Maebius
Attorney for Applicant
Reg. No. 42,967

Date: 3 October 2003
Hale and Dorr LLP
1455 Pennsylvania Ave., NW
Washington, D.C. 20004
(202) 942-8452